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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR     | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|--------------------------|---------------------|------------------|
| 09/830,986      | 05/03/2001  | Andreas Bernkop-Schnurch | 030560-056          | 7285             |

7590 03/27/2002  
Burns Doane Swecker & Mathis  
PO Box 1404  
Alexandria, VA 22313-1404

EXAMINER

WILLIS, MICHAEL A

ART UNIT PAPER NUMBER

1617

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/830,986

Applicant(s)

BERNKOP-SCHNURCH,  
ANDREAS

Examiner

Michael A. Willis

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 28-99 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 28-99 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

Applicant's response submitted 26 December 2001 is entered. Claims 1 and 28-99 are pending. Any previous rejections that are not restated in this Office Action are hereby withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Drawings***

See attached Form PTO 948: Notice of Draftsperson's Patent Drawing Review.

### ***Response to Arguments***

Claims 30, 50, 72, 74, 75, 82, 96, and 99 are rejected under 35 USC 112, second paragraph, for reasons as stated in a previous Office Action. Applicant argues that "derivatives" is defined in the specification. The definition says that derivatives are obtained by introduction of functional groups. However, it is not clear which functional groups are included in this definition.

1. Claims 1, and 28-32 are rejected under 35 USC 102(b) as being clearly anticipated by Constancis et al (US Pat. 5,496,872) for reasons as stated in a previous Office Action. Applicant argues that the polymers of Constancis have disulfide bonds, and as such, they do not exist as thiol groups. Applicant further argues that the term "mucoadhesive" in the preamble distinguishes applicant's invention from the prior art. Applicant's arguments have been considered, but are not convincing. First of all, it is the position of the examiner that the compounds

described by Constancis contain non-terminal thiol groups. For example, see Figure I in the abstract. The definitions of R1 and R2 clearly indicate that the substituents include SH groups. In response to applicant's arguments, the recitation "mucoadhesive" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

2. Claims 1 and 28-99 are rejected under 35 USC 103(a) as being unpatentable over Bernkop-Schnurch in view of Constancis for reasons as stated in a previous Office Action. Applicant's arguments with respect to the distinction between "bioadhesive" and "mucoadhesive" compositions is not found convincing.

The following new grounds of rejection is made:

***Claim Rejections - 35 USC § 102***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 28, 29, 31, 32, 33, 34, 35, 36, 37, and 38 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Moens (US Pat. 5,670,468). Moens

discloses thiol containing polymers including polycysteine (see col. 8, lines 12-15). The term "mucoadhesive" of the instant claims is not given patentable weight. The total work of adhesion is considered to be an inherent property of the compounds.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on Mon. to Fri. from 9 a.m. to 5:30 p.m.

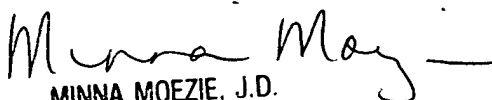
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.



Michael A. Willis  
Examiner  
Art Unit 1617

March 25, 2002



MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600